New York State Department of Health
2005 Guidance for HIV Counseling and Testing and New Laboratory Reporting Requirements: Questions & Answers

General Questions

1. What are the overall goals of the new Guidance?

a. To provide greater flexibility for pre-test counseling by allowing client-specific counseling, ranging from having an individual read Part A of the Informed Consent form to more extensive counseling for those who require more in-depth counseling.
b. To make HIV testing more routine in more settings to ensure people are diagnosed early and know their HIV status.
c. To ensure persons with HIV have ready access to HIV health care and services.
d. To ensure that persons with HIV in care are receiving high quality care.
e. To provide data on HIV incidence to help the Health Department guide HIV prevention programs.

2. Why is the NYS Department of Health taking these steps now? There are several reasons why these steps are timely. Extending the reach of HIV testing is needed because:

a. Up to 25% of persons with HIV don't know it and have never been tested (CDC, MMWR, 4/18/03).
b. About 40% of patients diagnosed with HIV progress to AIDS within one year (CDC, MMWR, 4/18/03).
c. The availability of new testing technologies such as rapid testing permit testing in a greater array of sites and settings and HIV incidence testing provides more information to understand the epidemic and to guide prevention efforts. CDC recommends making rapid tests available as they are more effective and efficient, providing preliminary test results quickly (CDC, MMWR, 11/22/02; CDC, MMWR, 4/18/03).
d. Recent studies published in "The New England Journal of Medicine" (Bozette, NEJM, 2005; Sanders et al., NEJM, 2005; Paltiel et al, NEJM, 2005) suggest that HIV screening is cost effective at much lower population prevalence than the 1% highlighted by the national Centers for Disease Control and Prevention (CDC).

Entering the third decade of HIV/AIDS, challenges include; assuring that those at risk of

contracting HIV are tested; ensuring rapid entry into care of persons diagnosed with HIV; the need for better monitoring of quality of care, both through provider-based quality assurance programs and better monitoring of CD4 progression and viral load suppression on a population basis; and the need for better monitoring of highly active antiretroviral therapy (HAART) resistence, in order to better inform clinical practice and public health measures to promote adherence. Delays in diagnosing HIV infection result in missed opportunities for treatment to maintain health, and the inability to apply prevention measures to prevent further transmission during the period of peak infectivity early in HIV illness.

3. What's new in the "2005 Guidance for HIV Counseling and Testing and New Laboratory Reporting Requirements" for health care providers? Health care providers are asked to integrate routine HIV testing in medical care and other service settings by expanding both sites in which testing is conducted and the populations to be tested. Recommendations for testing and for client-specific HIV pre-test counseling are also revised. There are no new reporting requirements for health care providers. Laboratory reporting is expanded to include viral resistance testing and viral load testing.

4. What changes have been made to Article 27F of the New York State Public Health Law? No changes were made to Article 27F of the Public health Law. The new Guidance and forms were possible within the flexibility of the existing Public Health Law Article 27F and required only minor changes to Part 63 regulations.

Streamlining HIV Pre-Test Counseling

5. What guidance does the Department offer providers surrounding when and when not to offer streamlined pre-test counseling? The 2005 Guidance highlights the flexibility that providers have to tailor HIV pre-test counseling to best meet the needs of individuals to be tested. Client-centered counseling, when possible, is recommended by the CDC, but not when it may be a barrier to the provision or acceptance of an HIV test. Decisions concerning tailoring the extent of pre-test counseling must be made on a case-by-case basis. HIV test providers must take a number of issues into consideration in determining whether or not streamlined pre-test counseling is appropriate. These considerations include such factors as the individuals' knowledge of HIV/AIDS, ability to independently review Part A of the Informed Consent form and testing history (if known).

In medical care settings, there may be information in the medical record that can help guide decisions about tailoring pre-test counseling. In non-clinical settings serving high-risk communities or populations, pre-test counseling should be tailored to the unique needs of the individual. Streamlined counseling should be seen as a minimum which may be expanded upon. For instance, providers serving persons at high risk may

be able to place greater emphasis on risk reduction counseling and/or use of behavioral interventions (i.e., stage-based counseling or motivational interviewing).

In all settings, individuals with limited literacy and individuals who, for whatever reason, may not quickly grasp the information about HIV testing and its consequences should be afforded more lengthy pre-test counseling. The Public Health Law provides individuals the ability to consent to an HIV test without regard to age. Care must be taken to assure that young persons seeking testing are able to make informed decisions about testing. In most cases, streamlined pre-test counseling of younger persons may not be appropriate.

In all cases, an overall goal is to assure that individuals are capable of providing informed consent for testing. If an individual is unable to understand, only a person legally authorized to consent may do so.

6. Doesn't the Public Health Law Article 27F require detailed, face-to-face counseling? No, Article 27F specifies the content of the counseling messages but doesn't specify how these messages are to be delivered. NYSDOH has held, for some time, that pre-test counseling messages should be tailored to client need but can be successfully delivered by 1) written materials, brochures, the Informed Consent form, etc., 2) video or audio materials, and/or 3) face-to-face counseling.

7. What does this new Guidance mean for the dedicated counselor model? Health care facilities that serve a high-risk clientele and that conduct a high volume of HIV tests may wish to retain a dedicated test counselor(s). In other clinical settings, having a counselor available to address the needs of those who receive positive test results and for addressing the prevention needs of high-risk individuals whose HIV test results are negative may be appropriate.

8. Has the Health Department said before that counseling does not have to be in-person? Yes, for the past five years the NYSDOH has encouraged streamlined counseling when appropriate using written materials, particularly in the prenatal care setting. This 2005 initiative expands this approach to other HIV counseling and testing settings.

9. Who should be recommended to get an HIV test? Prenatal care providers must recommend testing to all pregnant women regardless of risk. Testing should occur as early as possible in pregnancy and be repeated in the third trimester.

To encourage HIV testing more broadly, NYSDOH, consistent with the Centers for Disease Control and Prevention (CDC) Advancing HIV Prevention Initiative, encourages health care providers in NYS to routinely discuss and offer HIV testing to their patients, regardless of their perceived risk, and to have a low threshold for recommending HIV testing since not all infected persons are aware of or willing to disclose their risks.

Health care providers should recommend HIV testing, as appropriate, to all sexually active persons, persons with a history of substance abuse and persons in areas with high seroprevalence (i.e., at least 1%), including most major urban areas. Even in areas of low seroprevalence, many people, even with no identified risk factors, should be tested at least once during routine medical care. Recent published reports indicate that routine HIV testing at least once may be cost effective, even in areas with seroprevalence less than 1% (Bozette, NEJM, 2005; Sanders et al., NEJM, 2005; Paltiel et al, NEJM, 2005).

Routine testing should be recommended through managed care and fee-for-service providers at primary care sites, community health centers/diagnostic and treatment centers, urgent care centers, Designated AIDS Centers and other hospitals, substance abuse treatment programs, public STD clinics, family planning programs, correctional facilities and other settings. Testing in emergency rooms is also encouraged, particularly in areas of high seroprevalence and for individuals at high risk.

10. Are there any changes in billing procedures associated with this new guidance and streamlined counseling? No changes are being made at this time. Current billing procedures remain in effect. NYSDOH is looking at updating the current 15-year-old reimbursement system over the next year.

11. With the advent of rapid testing is it possible to bill Medicaid for visits for pre- and post-test counseling that occur in the same day? This was not an issue before the advent of rapid testing, since pre- and post-test counseling would occur on different days. Since May of 2003, participating providers in the HIV Primary Care Medicaid Program (HPCMP) have been allowed to bill a pre- and a post- HIV counseling and testing visit on the same day when HIV rapid testing technology is utilized. Information pertaining to the HPCMP as it relates to rapid testing may be found on the NYSDOH web site at:

http://www.health.state.ny.us/diseases/aids/testing/rapid/healthfac.htm

12. Is it possible to bill Medicaid for pre- and post-test counseling <u>as well as</u> another visit on the same day? Since providers will be integrating testing into more settings, it is possible that a patient might be visiting a specialist (e.g., for a dermatology visit) and then also undergo pre- and post-test counseling in the same day. Yes. The providers enrolled in the HPCMP are allowed to bill a non-HIV related visit with their HIV visit on the same day. Thus, it is possible for the provider to same-day bill a non-HIV visit (dermatology, etc.), along with the HIV pre- and post-test visits.

13. Are there any Medicaid requirements that counselors must have completed an AIDS Institute-approved course before Medicaid will reimburse for HIV C&T? Physicians have never been required to complete or attend the HIV

Counselor training. The policy on counselor training, included as item 10 in the agreement between the NYS Department of Health (NYSDOH) and facilities participating in the HIV Primary Care Medicaid Program, has been that:

> "The Provider agrees that, *unless specifically exempted in writing by the DOH*, all non-physician staff conducting HIV counseling shall complete a DOH-approved HIV counselor training program within twelve months of the effective date of this agreement. In addition, unless specifically exempted in writing by the DOH, staff participating in the Provider's in-service education programs, in facilities which have such programs, shall complete a DOH-approved HIV counselor train-the-trainer program."

This policy is inconsistent with efforts to routinize and normalize HIV testing and is being changed. Effective immediately training for non-clinical staff and staff who provide on site counselor training is **recommended** rather than **required**. This change is being communicated through a letter from NYS DOH to participating facilities, exempting them from training requirements.

14. In the context of streamlined pre-test counseling, what responsibility does the provider have to determine whether a client has the capacity to consent to an HIV test? In 2005, the benefits of HIV testing clearly outweigh the risks for the vast majority of people. To determine the capacity to consent, providers are encouraged to pose a simple question such as: “Do you understand what it means to have this test?” or “Do you have any questions before we go ahead and conduct the test?” It is assumed that most adults have the capacity to consent unless there is a reason to think otherwise.

When testing is conducted in the context of routine health care, the provider often has an existing relationship with the patient and has access to his/her medical history which may help the provider determine if the client has capacity to consent or not. Non-clinical settings targeting vulnerable populations (for example, youth, people with mental illness, or developmental disability) should consider tailoring the informed consent process when testing people for whom capacity to consent may be an issue.

Informed Consent Form

15. Why is the Department of Health issuing a new HIV testing Informed Consent form? A new Informed Consent form for HIV testing has been issued for a number of reasons. The old form addressed the HIV ELISA and Western Blot laboratory tests. Many new tests are now available. The new form has been made more comprehensive to reflect consent for new laboratory analyses and permits a patient to consent at one time for HIV diagnostic tests, as well as for medically recommended HIV drug resistance testing and for public health monitoring tests, as

recommended by the CDC to help guide HIV prevention efforts.

16. What specific tests does the Informed Consent form cover? What exactly is the individual being asked to consent to? Today, HIV testing involves a test to see if an individual has HIV infection (either an antibody test or a test for the virus, for example a PCR test) and a test to help the health department monitor the epidemic and guide prevention programs (for example, an HIV incidence test). HIV testing may also include a test(s) to help determine the best treatment (for example, antiretroviral resistance testing). The new Informed Consent form provides consent for an HIV antibody test or PCR/viral load test for diagnosis of HIV infection. For those who test negative, this is the only test consented for, no further testing will be conducted.

For those who test HIV positive, additional antiviral resistance testing may be conducted to help the physician determine the best course of treatment. In addition, a "STARHS" test will be conducted on the same specimen. STARHS stands for "Serologic Testing Algorithm for Recent HIV Seroconversion" and it refers to tests performed to obtain estimates of HIV incidence (recent HIV infection) that will be invaluable for public health planning to guide HIV prevention programs. STARHS testing uses a type of HIV antibody test that the FDA has designated as "for surveillance use only" because it is not reliable for an individual and as such is not useful for clinical care. For this reason, the STARHS test results are not returned to the patient or physician. No clinically useful test of HIV incidence is available.

In addition, for those who test HIV positive and enter health care, the Informed Consent form covers the medically recommended HIV drug resistance testing and viral load testing that may be obtained in the future. Covering this future testing in a single consent form is consistent with current medical practice. Persons with HIV can withdraw consent for this future testing at any time by talking to their health care provider and indicating that they do not wish to have viral load and/or viral resistance testing done. For those who test positive and do not enter care or who do not provide any additional specimen(s) for future testing, there will be no further testing conducted.

17. How is the new Informed Consent form intended to be used? The new HIV Informed Consent form is in two parts: Part A, which provides necessary information, and Part B, the signature page. Part A, the informational section, contains all of the basic information that someone would need to know to make a decision about being tested in simple, easy-to-follow language. For persons considering testing, this written document should be provided for review. Unless there are questions or other circumstances warranting further steps, individuals can be asked for their written consent on Part B and they should be encouraged to keep the informational section (Part A). The signature page, Part B of the new Informed Consent form, should be maintained by the provider.

18. What if the patient/client wants a copy of Part B of the Informed

Consent form? Patients/clients who want a copy of Part B of the Informed Consent form should be provided with a blank copy of Part B. In all cases individuals tested should be encouraged to retain Part A of the Informed Consent form. Part A does not contain any identifying information.

19. Can physicians continue to use the old HIV consent forms? Beginning June 1, 2005, all physicians must employ the new HIV Informed Consent form available on the Department of Health's web site at www.health.state.ny.us/diseases/aids/forms under "HIV/AIDS." Foreign language translations of the new form will be published on the web site as soon as possible. The old forms are not reflective of the new counseling and testing protocols and should not be utilized.

20. Which HIV tests require that the Informed Consent form be signed? Persons presenting for diagnostic HIV testing need to provide written informed consent using the DOH-approved Informed Consent form before HIV testing is done. In addition, pregnant women who sign the new Informed Consent form are also authorizing repeat HIV diagnostic testing at the discretion of their clinician for the duration of that pregnancy.

if an individual consents for testing and is found to have HIV infection, no additional written consent is needed for HIV testing used as part of routine medical care (viral load or resistance testing, for example).

21. The Informed Consent form states that additional testing may be done to help the Health Department guide HIV prevention programs, and the Commissioner's letter mentions incidence testing. What tests will be done for these purposes? By using new testing technology known as STARHS - STARHS is an acronym for "Serologic Testing Algorithm for Recent HIV Seroconversion" - on residual diagnostic sera from newly diagnosed persons and HIV testing history, the NYSDOH will be able to obtain estimates of HIV incidence that will be invaluable for public health planning. STARHS testing uses a type of HIV antibody test that the FDA has designated as "for surveillance use only" because it is not reliable for an individual and as such is not useful for clinical care. No clinically useful test of HIV incidence is available. CDC recommends use of these tests.

22. What if the client doesn't want to consent to STARHS testing? As noted in the question above, the STARHS test does not yield useful information for the client. FDA rules do not allow the test result to be returned to the client. The STARHS test result will be held by the DOH under the same strict confidentiality standards as other HIV related information. Individuals who are uncomfortable with STARHS testing can seek anonymous testing (STARHS testing will not be done unless the individual agrees to convert the result to a confidential test result) or other options, such as home specimen collection test kits. Testing in another state will not address this concern since HIV incidence surveillance using STARHS is a national program and all states are

conducting STARHS testing or will be in the future. Since CDC does not require states to get consent for STARHS testing, persons testing for HIV in other states may not be told that the testing will be done.

23. What options are available to an individual who wishes only to learn their HIV status but is not interested, willing nor ready to consent to viral load, CD4 or resistance testing? The language in the new consent form extends to tests beyond the diagnostic testing (such as viral load, CD4 and resistance testing) that are used to guide treatment decisions. However, tests for further medical evaluation would not be conducted at the same time as the diagnostic testing (unless the physician determines that it is medically compelling to expedite additional evaluation and orders additional tests, in which case the physician would discuss this with the patient). The typical scenario is that diagnosis would be confirmed and results returned to the client (with possible referral elsewhere) before further tests are ordered. In this typical case, the individual could decline to have an additional blood sample(s) drawn.

24. How can clients be assured that laboratories do not conduct any additional tests beyond the test(s) that have been requested? If the physician or other practitioner does not order a test, the laboratory cannot legally conduct it. As specified in NYS regulations (10NYCRR Subpart 58-1.7), only clinical laboratories under a permit may examine specimens for the purpose of diagnosis, prevention of treatment of disease or the assessment of a health condition. They may do so only at the request of a licensed physician or other person authorized by law to use laboratory findings in their practice or performance of official duties. Specimens submitted to clinical laboratories must be accompanied by test requisition forms that indicate the specific test(s) to be conducted. The NYSDOH Clinical Laboratory Evaluation Program sets forth minimum standards of performance and monitors the performance of clinical laboratories.

25. Does the practitioner that provides the patient with the printed Informed Consent form need to be certified as an HIV counselor? See number 13, above. Attendance at an HIV counselor training has not been a requirement for physicians who provide HIV Testing. Additionally, a recent change in the HIV Primary Care Medicaid Program (HPCMP) agreement rescinds the program requirement for the attendance at the DOH-sponsored HIV counselor training for all staff who provides HIV testing services. NYSDOH recommends that all non-clinician staff attend the HIV counselor training. It is <u>not</u> required.

26. Do patients need to provide written informed consent every time a viral load test is ordered? No. The new consolidated, comprehensive Informed Consent form includes viral load tests. Consequently, someone signing the new Informed Consent form is providing consent for viral load tests. Further, the NYSDOH recognizes that it is not the practice now to obtain written consent just for viral load tests and NYSDOH has no plan to require persons already in care and continuing to be monitored

via viral load tests, to sign written Informed Consent forms.

27. The Dear Colleague letter says that providers may use a "compatible version" of the Informed Consent form that is approved by the Department. How does one get a different form approved? The DOH strongly encourages use of the model forms appearing on the web site. However, anyone wishing to have different forms approved must send the forms and a request letter to: The Office of Counsel, NYSDOH, Rm 2438, Corning Tower, Empire State Plaza, Albany, NY 12237. Such requests and copies of proposed forms may also be faxed to: (518) 473-2019. The forms must conform to all requirements of Public Health Law Article 27-F. Anyone wishing merely to place the model forms on their letterhead may do so without additional approval.

28. Can e-mail be used to submit proposed versions of Informed Consent forms for DOH approval? No. Requests to use a provider-developed form must be in writing and either mailed or faxed as noted above.

29. Is the single Informed Consent form for multiple tests during prenatal care new? No, in 2004 the NYSDOH supplied prenatal care providers with a single consent form for multiple HIV antibody tests during the same pregnancy. It has been in use since that time.

30. Will the Informed Consent form be available in other languages soon? Yes, the Consent form is being made available in several other languages. Translations are being processed as soon as possible and versions of the Consent form in other languages are being posted on the web as soon as they become available. The web link is: http://www.health.state.ny.us/diseases/aids/forms/.

31. Will the Expedited Testing in Labor and Delivery consent form be updated to include some of the new information on the new consent form. Yes, this form is currently being updated by the NYSDOH AIDS Institute.

32. Will the current DOH occupational exposure consent form be revised? Yes. The "Informed Consent to Perform a Confidential HIV Test and Authorization for Release of HIV Related Information for Purposes of Providing Post-Exposure Care to a Health Care Worker Exposed to a Patient's Blood or Body Fluids" (DOH 4054) has been removed from the web site and discontinued as of June 1. In lieu of this, providers have been advised to use the "Informed Consent to Perform an HIV Test" and "Authorization for Release of Confidential HIV Related Information" and a link is provided on the forms page, leading to the new Informed Consent and HIPAA Compliant Release forms. A new consent form is being developed specifically for occupational exposures. It will be available later in 2005.

Please note that, existing NYS regulations Part 63.8(m) have permitted, since 2000, the

disclosure of HIV information without the sources person's consent in certain occupational exposure situations involving specified staff, pursuant to a protocol which includes documentation of the incident, investigation, a finding of significant risk and a request for disclosure made to the source person's health care provider. Consequently, if a source person consents to an HIV test, it is often more expeditious and less administratively burdensome to obtain, at the same time, an authorization from the source person to disclose the test result to the exposed person. However, even if the source refuses to authorize disclosure, disclosure of HIV test results in a medical record can be made to exposed persons provided the Part 63.8(m) protocol and documentation is complied with. For details concerning applicable requirements please see Part 63.8(m) at:

http://www.health.state.ny.us/nysdoh/phforum/nycrr10.htm

HIV Post-Test Counseling

33. Has HIV post-test counseling changed? No changes are being made to the post-test counseling process. Individuals who receive negative test results should be provided with their results and encouraged to retain Part A of the Informed Consent form. For individuals with identified risks, other relevant information should be provided and these individuals should be encouraged to access HIV prevention programs and services appropriate to their risk(s).

Individuals who receive positive test results should be provided with post-test counseling consistent with existing Public Health Law section 2781 and Part 63 regulations. Post-test counseling for persons learning of their HIV infection must address a number of issue areas including: coping with the consequences of learning the result; potential for discrimination; prevention of transmission of HIV to others; access to medical care; the need to notify partners, contacts and spouses including notification options and screening for risk of domestic violence; that HIV reporting is required by law; access to prevention services and assistance, if needed, in obtaining any of these services; and proactive assistance for accessing care, prevention and supportive services.

HIPAA Compliant Authorization for the Release of Medical Information and Confidential HIV-Related Information

34. Why is the Department of Health issuing a new HIV release of information form, different from the one previously located in the Health Department regulations? The HIV release form currently in the regulations is not compliant with federal Health Insurance Portability and Accountability Act ("HIPAA") privacy regulations. HIPAA has specific requirements for "authorizations" for the

release of health information. Consequently, the new HIV release form is HIPAA compliant and may be utilized for the release of health information.

To facilitate referrals and access to care and services, the new *HIPAA Compliant Authorization for the Release of Medical Information and Confidential HIV-Related Information* allows individuals to use a single form to authorize release of general medical information as well as HIV-related information to more than one provider and to authorize providers to share information between and among themselves. These enhancements were made to facilitate access to care and services and to minimize the number of forms that have to be completed.

35. Page 1 of the Release Form has a section for "Description of the consequences, if any, of failing to consent to disclosure upon treatment, payment, enrollment, or eligibility for benefits..." This is confusing. How should this section be completed? These statements are required by federal regulations to appear on all HIPAA compliant release forms and they have appeared on such forms since April 2003. The intent is to promote full disclosure of possible consequences, if any, of failing to release general medical and/or HIV-related medical information. This is important when failure to release information will have an impact on access to care or services, eligibility for housing, eligibility for entitlements, enrollment in clinical trials or research protocols, payment, etc. Examples of possible responses to this question are: "No consequences." "Not applicable." "Information required to access housing benefits." "Information required for the coordination of care and services." or "Information required to participate in clinical trials and access free medications."

36. How and for what purposes should the revised HIPAA- Compliant Authorization for Release of Medical Information and Confidential HIV-Related Information be Used? This form, which replaces an existing form that only allowed release of HIV-related information, has been revised to allow release of BOTH non-HIV and/or HIV-related information as a means of minimizing the number of forms that must be completed for each client. This form also allows information to be released to more than one facility or person and, if authorized by the client, for these facilities and persons to share information between and among themselves. As an example, if an individual's primary care provider is referring him/her to a specialist and to a case manager, this form can be used to authorize the individual's medical and/or HIV-related medical information to be shared with both providers and for these providers to talk with one-another regarding care and treatment of the subject of this information.

There may be circumstances in which an individual or provider only wants to release non-HIV related medical information. In these situations, either this form or another approved HIPAA-compliant general medical release form may be used.

37. Can disclosure of HIV information occur based on a photocopy or a fax of an executed HIV Release form? Yes, unless there is some reason to suspect that the copy or fax of a Release is false or inaccurate, a provider, acting in good faith, may release HIV information based upon a photocopy or a fax of an executed Release.

38. Federal regulations protect the identity of an individual receiving drug or alcohol treatment. Can providers use the NYSDOH *HIPAA Compliant Authorization for the Release of Medical Information and Confidential HIV-Related Information* for disclosure of information if such disclosure identifies an individual as receiving drug or alcohol treatment? Yes. The *HIPAA Compliant Authorization for the Release of Medical Information and Confidential HIV-Related Information* may be used to disclose information that identifies that an individual is in treatment and/or information about that person's treatment as long as it is accompanied by a notice prohibiting redisclosure of the information concerning alcohol or other drugs (AOD). The NYS Office of Substance Abuse Services has such a notice available for use by providers. The OASAS form TRS-1, "Prohibition on Redisclosure of Information Concerning Alcoholism and Substance Abuse Patient" is available in both English and Spanish on the OASAS web site at:

http://www.oasas.state.ny.us/mis/forms/trs/trs-1eng.pdf.

This form must accompany all disclosures/releases of information concerning substance abuse patients. Questions concerning this form may be directed to OASAS at: forms@oasas.state.ny.us.

39. State law and regulations prohibit disclosure of HIV-related information. What's to prevent the recipient of information disclosed pursuant to a signed Release from redisclosing the confidential HIV-related information? When written material is sent pursuant to a signed *HIPAA Compliant Authorization for the Release of Medical Information and Confidential HIV-Related Information* it must be accompanied by a notice that states: "This information has been disclosed to you from confidential records which are protected by state law. State law prohibits you from making any further disclosure of this information without the specific written consent of the person to whom it pertains, or as otherwise permitted by law. Any unauthorized further disclosure in violation of state law may result in a fine or jail sentence or both. A general authorization for the release of medical or other information is NOT sufficient authorization for further disclosure."

40. If we are currently releasing information under the auspices of a Release form signed prior to June 1, 2005 do we have to go through all of our files to identify each and every case for which we would need to get another Release form signed? Providers who are not HIPAA-covered entities (e.g., who do not bill electronically or who hire firms who bill electronically for them) may continue to use the NYSDOH HIV Release form which previously appeared in the regulations. HIV Release

forms which first appeared in 2003 on the DOH web site at www.health.state.ny.us are HIPAA compliant and can continue to be used by HIPAA-covered entities. The new form which is not only HIPAA compliant, but also permits the patient, with a single form, to authorize the release of HIV and other protected health information to multiple providers or facilities. Release forms that indicate that information may be released beyond June 1, 2005 may continue to be used until the specified end date. Beginning June 1 the new forms should be phased in, as appropriate.

Reporting Requirements for Laboratories

41. How do HIV reporting requirements for laboratories change with the new regulations? New NYSDOH laboratory reporting requirements for New York State residents include electronic reporting of (1) nondetectable HIV nucleic acid tests, (2) base sequences from genotypic resistance tests, and (3) all CD4 tests. Laboratories should continue the established electronic reporting of the following tests to the New York State Department of Health: confirmatory HIV antibody tests and detectable HIV nucleic acid tests. For assistance in complying with reporting requirements, laboratories should contact the NYSDOH Bureau of HIV/AIDS Epidemiology at (518) 474-4284.

42. Do HIV reporting requirements for health care providers change with the new regulations? No. Additional information on existing guidelines for reporting of HIV and AIDS cases using DOH form DOH-4189 can be obtained from the NYSDOH Bureau of HIV/AIDS Epidemiology at (518)474-4284 or from the NYSDOH web site at: http://www.health.state.ny.us/diseases/aids/regulations/

43. How will individuals already in care for HIV/AIDS find out about the new reporting provisions? Medical providers should take time to explain the additional reporting requirements to individuals already in care. The Department of Health is providing a simple, 1-page hand out to help facilitate this discussion and is working with the Medical Society of the State of New York (MSSNY) to reinforce the importance of this and other-related medical care issues.

44. Why is the health department requiring laboratories to report only reverse transcriptase and protease inhibitor genotypes for resistance reporting? The NYSDOH is requiring public health reporting of HIV antiviral resistance testing to answer several questions about the overall status of the epidemic. The questions include: 1) How often are resistant viruses transmitted, including those with high level (3-drug class) resistance? 2) How often does resistance occur in those chronically infected with HIV? 3) How many people with long-standing HIV or AIDS have 3-drug class resistance that severely limits treatment options? The answers to these questions will help guide prevention and resource planning.

The new regulations call for laboratories to report "resistance testing in a format designated by the Commissioner." Two types of resistance testing for reverse transcriptase and protease antiviral agents (genotypic and phenotypic) are currently in common clinical use. Resistance testing reporting will be implemented with the nucleotide sequence from genotypic testing for reverse transcriptase and protease inhibitor resistance because 1) it is the most commonly used type of resistance testing, particularly in the newly diagnosed or less treatment-experienced person; 2) the sequence can easily be transmitted electronically; 3) the DOH can use a single interpretation algorithm to analyze the data, thus diminishing variations in interpretation among laboratories and methodologies.

In complicated clinical situations and in clinical trials, extensive evaluation of resistance patterns, viral fitness, receptor status, and other viral characteristics may be desirable. The NYSDOH may expand reporting as these tests become standardized if more or different information is needed to answer the questions noted above.

45. Sometimes physicians order HIV viral load testing in follow up to a negative antibody test to rule out early infection. In most cases, the viral load result is below detectable; if it were truly negative (the person is not infected) the result would be the same, that is, below detectable. Are viral load results generated under these circumstances reportable? Yes, this is reportable. All detectable and non-detectable HIV viral load test results are reportable.

46. Will NYSDOH take steps to assure that the truly negative person's viral load test result is sorted out from other below detectable viral loads to avoid the truly negative person being contacted for public health purposes? Yes. The follow-up will occur upon chart review by the public health representative. At that time a determination will be made about the case. The person found to be truly negative would not be added to the HIV/AIDS Registry. This is exactly the same process that has been followed with CD4 test results since June 2000.

Other Questions

47. What should someone do if HIV counseling and testing is not conducted in accordance with Article 27F? How does the Health Department become aware of these instances? For complaints involving patient care in licensed facilities, the complainant should be referred to the following phone numbers as applicable:

Hospitals, Diagnostic and Treatment Centers (D&TC), and Adult Day Health Care

1-877-249-5115 (Toll free)
1-212-417-5995 (Metropolitan New York Region)

1-716-423-8049 (Western Region)
1-518-271-2610 (Capital Region)
1-315-426-7696 (Syracuse Region)

Nursing Facilities and Adult Day Health Care: 1-800-425-0316
Regarding Care Rendered by a Physician or Physician's Assistant: 1-800-663-6114

The NYS Department of Health accepts anonymous complaints and complaints on behalf of a client from a family member, guardian, significant other, partner, caregiver or others who have a relationship to the client/patient. In cases where a complaint is submitted on behalf of a client, Department staff will generally ask to discuss the complaint with the client.

48. I have a question that is not reflected here. How can I obtain an answer? Questions may be submitted by email to HIVET@health.state.ny.us. All questions will be reviewed and responded to. Frequently asked questions will be added to the web-based version of this Q&A that is posted on the NYSDOH web site.